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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 09/068,935 | 11/23/98 | PASCUAL D | 47714-5004 |

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| EXAMINER | |
|---|---|
| GAMBEL, P | |
| **ART UNIT** | **PAPER NUMBER** |
| 1644 | 28 |

**DATE MAILED:** 08/29/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

| Application No. | Applicant(s) |
|---|---|
| 09/068935 | PASCUAL |
| **Examiner** | **Group Art Unit** |
| GAMBEL | 1644 |

*—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

**Status**

☑ Responsive to communication(s) filed on 5/1/00.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

**Disposition of Claims**

☑ Claim(s) 1-54 is/are pending in the application.

Of the above claim(s)_____ is/are withdrawn from consideration.

☐ Claim(s)_____ is/are allowed.

☐ Claim(s)_____ is/are rejected.

☐ Claim(s)_____ is/are objected to.

☑ Claim(s) 1-54 are subject to restriction or election requirement.

**Application Papers**

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on_____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on_____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119 (a)-(d)**

☑ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☑ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number)_____.

☑ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received:_____.

**Attachment(s)**

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s)._____

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other_____

**Office Action Summary**

## DETAILED ACTION

1. Applicant's submission, filed 5/1/00 (Paper No. 12), is in compliance with the Sequence Rules.

2. The numbering of claims is not accordance with 37 C.F.R. 1.126. The original numbering of the claims must be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When claims are added, except when presented in accordance with 37 CAR 1.121(b), they must be renumbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

The claim between claims 40 and 41 was not numbered and has been numbered claim 41.

Misnumbered claims 41-54 have been renumbered 42-55.

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CAR 1.499, applicant is required in response to this Office Action, to elect a single invention to which the claims must be restricted.

I. Claims 1-49, drawn to vaccines comprising attachments molecules, classified in Class 424, subclass 184.1.

II. Claims 50-53, drawn to a method of obtaining a vaccine comprising isolating a PAM and developing antibodies thereto, classified in Class 424, subclass 130.1.

III. Claims 54-55, drawn to a method of obtaining a vaccine comprising isolating a molecule which mimics a pathogen adhesion molecule and incorporating said molecule into a vaccine, classified in Class 424, subclass 184.1.

4. The invention of Group I (e.g. claim 1) was found to have no special technical feature that defined a contribution over the prior art of Bevilacqua et al. (U.S. Patent No. 5,081,034) AND/OR (WO94/05269; Centocor) as set forth in 206/210 Reports (see PCT 210 Search Report).

Bevilacqua et al. (U.S. Patent No. 5,081,034; see entire document) teach ELAM-1 and fragments thereof in pharmaceutical compositions to treat various disorders including the treatment of microbial infections (columns 13-14) as well as diagnostic assays to detect ELAM-1 with specific antibodies (columns 10-12). Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations addressed by the applicant would be inherent properties of the referenced ELAM-1-specific compositions and assays.

Heavner et al. (WO 94/05269; see entire document) teach E-selectin pharmaceutical compositions to treat various disorders including the treatment of bacterial sepsis (pages 19- 22) as well as diagnostic assays to detect ELAM-1 with specific antibodies (pages 22-23). Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations addressed by the applicant would be inherent properties of the referenced E-selectin-specific compositions and assays.

Therefore, the Invention of Group I has bee previously described.

Since applicant's Inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and lack Unity of Invention.

No Information Disclosure Statement has been filed with the instant application.
Bevilacqua et al. (U.S. Patent No. 5,081,034) and (WO94/05269; Centocor) have not been provided herein, as they were cited in PCT 210 Search Report of the priority document.

5. In addition to electing a Group from above, applicant is required to elect a species as follows.

A. This application contains claims directed to the following distinct species of Groups I/II/III, wherein the attachment molecule is selected from the group consisting of:
(1) proteins, glycoproteins, (2) glycolipids or (3) carbohydrates.

These species do not share the same or corresponding special technical feature because these species are distinct because their structures and modes of action are different which, in turn, address different pathological conditions and therapeutic endpoints.

B). This application contains claims directed to the following distinct species, wherein the targeted host cells for an attachment molecule is selected from the group consisting of:
(1) leukocytes, (2) endothelial cells, (3) epithelial cells, or (4) cells of the nervous system.

These species do not share the same or corresponding special technical feature because these species are distinct because these targeted structures and modes of action are different which, in turn, address different pathological conditions and therapeutic endpoints.

C). In addition to choosing a targeted cell type, this application contains claims directed to the following distinct species, wherein the targeted ligand is selected from the group consisting of:
(1) N-acetylneuraminic acid, (2) sialic acid, (3) N-acetylglucosamine or glucosamine, (4) N-acetylgalactosamine or galactosamine, (5) galactose, (6) mannose, (7) fucose or (8) lactose.

These species do not share the same or corresponding special technical feature because these species are distinct because their structures and modes of action are different which, in turn, address different pathological conditions and therapeutic endpoints.

D) If applicant elects a protein/glycoprotein, this application contains claims directed to the following distinct species, wherein the attachment molecule is selected from the group consisting of:
(1) selectin or integrin, (2) cytokine, (3) chemokine, or (4) GTP-binding protein.

These species do not share the same or corresponding special technical feature because these species are distinct because their structures and modes of action are different which, in turn, address different pathological conditions and therapeutic endpoints.

E) If applicant elects a GTP-binding protein, this application contains claims directed to the following distinct species, wherein the attachment molecule is selected from the group consisting of:
1) Rho, (2) Ras, (3) Rac, (4) Cdc42, (5) Rab, (6) Ran or (7) Arf.

These species do not share the same or corresponding special technical feature because these species are distinct because their structures and modes of action are different which, in turn, address different pathological conditions and therapeutic endpoints.

F) If applicant elects a selectin/integrin then this application contains claims directed to the following distinct species, wherein the attachment molecule is selected from the group consisting of:
(1) E-selectin, (2) P-selectin, (3) L-selectin, (4) VLA-1, (5) VLA-2, (6) VLA-3, (7) VLA-4, (8) VLA-5, (9) VLA-6, (10) Mac-1, (11) LFA-1, (12) gp150.95, (13) CD41a, (14) CD49, (15) CD51, (16) ICAM-1, (17) ICAM-2, (18) ICAM-3, (19) VCAM, (20) NCAM or (21) PECAM

These species do not share the same or corresponding special technical feature because these species are distinct because their structures and modes of action are different which, in turn, address different pathological conditions and therapeutic endpoints.

G) This application contains claims directed to the following distinct species, wherein the attachment molecule is selected from the group consisting of the microbes selected from the group of: (1) E. coli, (2) Salmonella, (3) Shigella, (4) Pseudomonas, (4) Proteus, (5) Klebsiella, (6) Aerobacter, (7) Heliobacter, (8) Plasmodium, (9) Brucella, (10) Pasteurella, (11) Leishmania, (12) Trypanosoma, (13) Mycobacterium TB, (14) Legionella, (15) Staphylococcus, (16) Streptococcus, (17) Bordetella, (18) Hemophilus, (19), Aspergillus, (20) Cryptococcus, (21) Candida, (22) Histoplasma, (23) Coccidioides, (24) Phycomycetes, (25) Entamoeba, (26) Giardia, (27) Cryptosporidium, (28) Neisseria, (29) Chlamydia, (30) Treponema, (31) Trichomona, (32) Tritrichomonas, (33) Influenza A, (34) Influenza B, (35) Influenza C, (36) Measles, (37) Mumps, (38) Adenovirus, (39) Rhinovirus, (40), Poliovirus, (41) Hepatitis, (42) Hantavirus, (43) Herpesvirus, (44) Rubella, (45) HIV, Coxsackievirus, (46) Corynebacterium, (47) Clostridium, (48) Yersinia, (49) Vibrio, (50) Entamoeba or (51) Hafnia.

These species do not share the same or corresponding special technical feature because these species are distinct because their structures and modes of action are different which, in turn, address different pathological conditions and therapeutic endpoints.

Applicant should elect a species from (A), (B) and (G) as a single group and in addition, select an additional species from (C), (D), (E) or (F) as appropriate.

6. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Serial No. 09/068935
Art Unit 1644

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

PHILLIP GAMBEL

Phillip Gambel, PhD.
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Technology Center 1600
August 28, 2000